May 28, 2024

Orthofix, Inc.
Tony John
Regulatory Affairs Program Manager
3451 Plano Parkway
Lewisville, Texas 75056

Re: K240749
Trade/Device Name: PILLAR SA Ti Spacer System (82-XXX)
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVD
Dated: March 13, 2024
Received: March 19, 2024

Dear Tony John:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Brent Showalter -S

Brent Showalter, Ph.D.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

Device Name

PILLAR SA Ti Spacer System (82-XXX)

Indications for Use *(Describe)*

The PILLAR SA Ti Spacer System when used with screws is a standalone interbody implant indicated for use as an adjunct to fusion in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDD patients may also have up to Grade 1 spondylolisthesis at the involved level(s). Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the device.

The interbody is intended to be used with autogenous bone graft and/or allogeneic bone graft composed of cancellous, cortical, and/or corticocancellous bone. The The PILLAR SA Ti Interbody may be used as a standalone device only when at least two Screws are inserted with one inferior and one superior screw trajectory. If the surgeon chooses to use the PILLAR SA Ti Interbody with fewer than two Screws inserted with one inferior and one superior screw trajectory, then additional supplemental fixation system must be used. Hyperlordotic sizes (greater than 20°) are intended for use with supplemental fixation.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) Summary

Prepared on: 2024-03-19

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Orthofix, Inc.
Applicant Address	3451 Plano Pkwy Lewisville TX 75056 United States
Applicant Contact Telephone	214-937-2153
Applicant Contact	Mr. Tony John
Applicant Contact Email	TonyJohn@orthofix.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	PILLAR SA Ti Spacer System (82-XXX)
Common Name	Intervertebral body fusion device
Classification Name	Intervertebral Fusion Device With Bone Graft, Lumbar
Regulation Number	888.3080
Product Code	MAX

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K200052	PILLAR SA PTC Spacer System	MAX
K222732	WaveForm A Interbody System	MAX
K082235	PILLAR AL Spacer System	MAX

Device Description Summary

21 CFR 807.92(a)(4)

The PILLAR SA Ti Spacer System is an integrated intervertebral body fusion device for use in anterior lumbar interbody fusion (ALIF) procedures. The PILLAR SA TI Spacer System is comprised of 3D printed titanium interbody spacers with porous titanium end plates and a functional gradient porous structure, and bone screws. The implants are offered in multiple footprints and lordotic options to accommodate individual patient anatomy. Each porous interbody has a large central window for graft material and a threaded hole with a zero-step locking mechanism for screw retention.

The PILLAR SA TI Spacer System implants are provided sterile.

PILLAR SA TI Spacer System implants are designed to be used with PILLAR SA TI Spacer System instrumentation and are not compatible with components from any other manufacturer's system.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The PILLAR SA Ti Spacer System when used with screws is a standalone interbody implant indicated for use as an adjunct to fusion in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDD patients may also have up to Grade 1 spondylolisthesis at the involved level(s). Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the device.

The interbody is intended to be used with autogenous bone graft and/or allogeneic bone graft composed of cancellous, cortical, and/or corticocancellous bone. The The PILLAR SA Ti Interbody may be used as a standalone device only when at least two Screws are inserted with one inferior and one superior screw trajectory. If the surgeon chooses to use the PILLAR SA Ti Interbody with fewer than two Screws inserted with one inferior and one superior screw trajectory, then additional supplemental fixation system must be used. Hyperlordotic sizes (greater than 20°) are intended for use with supplemental fixation.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The subject PILLAR SA Ti Spacer System has the same intended use and comparable indications for use to the cited predicate devices.

Technological Comparison 21 CFR 807.92(a)(6)

The subject PILLAR SA Ti Spacer System the same: intended use, target population, method of fixation, surgical approach, sterilization, materials and general design elements as the cited PILLAR SA PTC Spacer System (K200052) and Meridian Interbody System (K233694) predicate devices.

In addition, Orthofix conducted the following mechanical tests as detailed in FDA Guidance "Class II Special Controls Guidance Document: Intervertebral Body Fusion Device" comparing the subject and predicate device:
• Static and Dynamic Axial Compression (ASTM F2077)
• Static and Dynamic Axial Compression Shear (ASTM F2077)
• Subsidence (ASTM F2267)
• Wear Evaluation (ASTM F1877)
The mechanical testing adequately demonstrated that the PILLAR SA Ti Spacer System implants (device under review) tested as well or better than the cited predicate devices.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Orthofix conducted the following mechanical tests as detailed in FDA Guidance "Class II Special Controls Guidance Document: Intervertebral Body Fusion Device" comparing the subject and predicate devices:
• Static and Dynamic Axial Compression (ASTM F2077)
• Static and Dynamic Axial Compression Shear (ASTM F2077)
• Subsidence (ASTM F2267)
• Wear Evaluation (ASTM F1877)
The mechanical testing adequately demonstrated that the PILLAR SA Ti Spacer System implants (device under review) tested as well or better than the cited predicate devices.

The mechanical testing adequately demonstrated that the PILLAR SA Ti Spacer System implants (device under review) tested as well or better than the cited predicate devices.